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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,368	11/24/2003	John C. Hegenauer	3790-66390-01	4632
24197	7590	04/17/2006	EXAMINER	
KLARQUIST SPARKMAN, LLP 121 SW SALMON STREET SUITE 1600 PORTLAND, OR 97204			COE, SUSAN D	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/722,368	Applicant(s) HEGENAUER ET AL.	
	Examiner Susan D. Coe	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005 and 17 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 18-74, 87 and 88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-17 and 75-86 is/are rejected.
- 7) ☐ Claim(s) 6 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/04 & 2/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-88 are currently pending.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-18 and 75-88 and corosolic acid for species A in the replies filed on December 27, 2005 and February 17, 2006 is acknowledged. The traversal is on the ground(s) that a search of the composition would overlap with the method of use; thus, a search of both would not be burdensome. This is not found persuasive because while a search of both groups might overlap to some extent, it would not necessarily be coextensive. In addition, the applicant argues that a search of all of the species would not be burdensome; however, the search of each species would require a separate search to fully examine search different group of species. Thus, burden is present.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 18-74, 87 and 88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the replies filed on December 27, 2005 and February 17, 2006.
4. Claims 1-17 and 75-86 are examined on the merits.

Claim Objections

5. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In claim 7, the amount of acacia gum can be as high as 16%. This is outside the range set forth in claim 6 where the highest amount of acacia gum is 15%. Thus, claim 7 improperly broadens the scope of claim 6.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 8, and 81-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 7 and 8 are rendered indefinite by the use of parentheses. The use of parentheses are considered indefinite because it is unclear if the enclosed limitation is or is not a required part of the claim.

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8. Claim 81 is indefinite because it refers to 120 grams of chromium. The use of “grams” does not have clear basis. Previous claims refer to micrograms rather than grams. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-3 and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat.

No. 6,150,399.

US '399 teaches a composition comprising 28 kg or 117.6 kg of soy protein and 1 gram or 250 mg of chromium chloride (see tables 3 and 4).

The reference does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

In addition, the reference does not state that the composition is a kit with written instructions as claimed by applicant. However, written instructions reciting an alleged novel use of a composition do not change the composition itself. *See, e.g., In re Haller* 73 USPQ 403, at

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404 (CCPA 1947) (“Accordingly, the mere labeling of an old composition as an insecticide does not make it a new or different composition within the meaning of the patent statutes.”) and *In re Ngai* 70 US PQ2d 1862 (CAFC 2004).

10. Claims 1-3 and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,514,656.

US ‘656 teaches a composition that contains 15.83 to 68.9 grams of protein. 60% of this protein is soy protein. The composition also contains up to 199.8 micrograms of chromium.

The reference does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant’s invention functions as claimed.

In addition, the reference does not state that the composition is a kit with written instructions as claimed by applicant. However, written instructions reciting an alleged novel use of a composition do not change the composition itself. *See, e.g., In re Haller* 73 USPQ 403, at 404 (CCPA 1947) (“Accordingly, the mere labeling of an old composition as an insecticide does not make it a new or different composition within the meaning of the patent statutes.”) and *In re Ngai* 70 US PQ2d 1862 (CAFC 2004).

11. Claims 75 and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. Pub. No. 2002/0197331.

US ‘331 teaches a nutritional composition that contains soy protein and chromium picolinate (see paragraph 136).

The reference does not specifically teach that the composition has the same effects on the body as those claimed by applicant; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to have the same effects if applicant's invention functions as claimed.

In addition, the reference does not state that the composition is a kit with written instructions as claimed by applicant. However, written instructions reciting an alleged novel use of a composition do not change the composition itself. *See, e.g., In re Haller* 73 USPQ 403, at 404 (CCPA 1947) ("Accordingly, the mere labeling of an old composition as an insecticide does not make it a new or different composition within the meaning of the patent statutes.") and *In re Ngai* 70 US PQ2d 1862 (CAFC 2004).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-5, 10, 11, and 75-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,858,449 and Grant et al. (Medicine and Science in Sports and Exercise (1997), vol. 992-998).

US '449 teaches a composition that contains soy protein that is used to induce weight loss. The composition contains 35 to 46% of the soy protein. The composition is provided in a 30 gram serving. Thus, 10 to 14 grams of soy protein are in the composition (see Example 4, column 22 and 23).

Grant teaches using chromium picolinate and chromium nicotinate to aid in weight loss. Up to 400 micrograms of chromium is administered per day (see entire document).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients to induce weight loss. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used to induce weight loss, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to induce weight loss.

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Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

The reference do not specifically teach adding the ingredients in the amounts claimed by applicant or making a product with the specific calorie amounts claimed by applicant. The amount of a specific ingredient in a composition or the calorie content of a weight loss composition are clearly a result effective parameters that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add and the optimal calorie amount to use in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient and calorie amount would have been obvious at the time of applicant's invention.

In addition, the references does not state that the composition has written instructions as claimed by applicant. However, written instructions reciting an alleged novel use of a composition do not change the composition itself. See, e.g., *In re Haller* 73 USPQ 403, at 404 (CCPA 1947) ("Accordingly, the mere labeling of an old composition as an insecticide does not

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make it a new or different composition within the meaning of the patent statutes.”) and *In re Ngai* 70 US PQ2d 1862 (CAFC 2004).

13. Claims 12-17 and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,858,449 and Grant et al. (Medicine and Science in Sports and Exercise (1997), vol. 992-998) as applied to claims 1-5, 10, 11, and 75-82 above, and further in view of US Pat. No. 6,784,206.

As discussed above, the combination of US ‘449 and Grant is considered to teach the combination of soy protein and chromium. However, the references do not teach adding corosolic acid or a banaba leaf extract that contains corosolic acid to the composition. US ‘206 teaches using a corosolic acid containing extract from *Lagerstroemia speciosa* (banaba leaf) to induce weight loss. 16 to 48 mg is administered (see columns 3 and 4). As discussed above, it is considered obvious to combine together ingredients that are known in the art to have equivalent purposes. Thus, a person of ordinary skill in the art would be motivated to add a corosolic acid containing banaba leaf extract to the soy protein and chromium because they are all known to be used for the same purpose.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been

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customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

14. No claims are allowed. However, claims 6-9 are considered free of the art and would be allowable if amended to overcome the above claim objections and 112 2nd rejections. The prior art teaches that all of these ingredients in these claims are nutritionally acceptable; however, there is no specific motivation to select these specific ingredients for combination in the specifically claimed amounts.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 9:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey, can be reached at (571) 272-0775. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.

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Susan D. Coe
Primary Examiner
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